SureTek Medical 510(k) Summary K052690

Submitter	SureTek Medical 25-B Maple Creek Circle Greenville, SC 29607
Contact	Mike Sammon, Ph.D. Phone: 864-299-9743 MAY 12 2006
Date	9/25/05
Product	SureTek Reprocessed Electric Laparoscopic Instruments
Classification	Code: NUJ Regulation: 21 CFR 878.4400 Name: Electrosurgical, cutting & coagulation accessories, laparoscopic & endoscopic, reprocessed.

Predicate Devices

Mfr/Reprocessor	Device/System Trade Names	510(k)
AutoSuture/US Surgical	EndoDissect*, EndoShears*	K951589
ConMed	Scissors and Dissectors	K924469
Ethicon	EndoPath* Scissors and Dissectors	K984240, K960476
Gyrus	Everest Bicoag*, Gyrus PlasmaKinetic*	K031085, K031079
Vanguard Medical	Reprocessed Instruments	K012700
Alliance Medical	Reprocessed Electrosurgical Instruments	K012603
SterilMed	Reprocessed Laparoscopic Instruments	K023986
MediSISS	Reprocessed Electrosurgical Instruments	K031869

Product Description, Technological Features

Devices are monopolar and bipolar instruments designed for resection, grasping, dissection and cauterization of tissue during general and laparoscopic surgery. Instruments consist of a proximal actuation handle with electrical connections to a compatible electrosurgical unit; an insulated shaft sized 3-10mm diameter and 15-45cm length; and a distal instrument configured as scissors, graspers, forceps and retractable needles or blades. Monopolar instruments require concurrent use of a compatible return electrode. Reprocessed instruments have equivalent technological characteristics as the predicate devices, as the device design, dimensions, energy delivery and system compatibility are unchanged during reprocessing. Device materials are identical with the exception of shaft insulation, which is replaced on monopolar instruments with a comparable FEP heat shrink tubing.

Intended Use

SureTek Reprocessed Laparoscopic Instruments are intended for use during general and laparoscopic surgery for cutting, grasping, dissection and electrocautery of tissue.

Testing and Standards

- Simulated-use testing of instruments following maximum number of use and reprocessing cycles found their performance to be substantially equivalent to new, unused devices.
- Product insulation conforms to the relevant safety requirements of ANSI/AAMI HF18 *Electrosurgical Devices.*
- SureTek cleaning process is validated to be effective for decontamination of grossly contaminated instruments under worst case operational conditions.
- Product packaging conform to all relevant requirements of ISO 11607 *Packaging for terminally sterilized medical devices*, with performance qualifications tested according to EN868-1 and ASTM F88-00, F2906-04, D4169-04a and F1980-02.
- Product sterility and process validation conform to the relevant requirements of ISO 11135 *Medical Devices – Validation and routine control of ethylene oxide sterilization.*
- Products conform to the relevant requirements of ISO 10993 *Biological Evaluation of Medical Devices* for ethylene oxide residuals and biocompatibility of device materials.

Substantial Equivalence Determination

Product testing and comparisons of specifications demonstrate that SureTek Reprocessed Electric Laparoscopic Instruments are substantially equivalent to their predicate devices with respect to device design, technological characteristics, intended use and performance, as well as product packaging, labeling, sterility and biological safety.

* Product tradenames are registered trademarks of their respective manufacturers.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 12 2006

Suretek Medical
% Mike Sammon, BME, Ph.D.
CEO/President
25-B Maple Creek Circle
Greenville, South Carolina 29607

Re: K052690
Trade/Device Name: SureTek Reprocessed Laparoscopic Instruments
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: NUJ
Dated: January 3, 2006
Received: January 6, 2006

Dear Dr. Sammon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Reprocessed Laparoscopic Instruments found to be substantially equivalent:

AUTOSUTURE	ENDO DISSECT 5mm	Monopolar, 33cm Length
AUTOSUTURE	ENDO SCIZ 5mm	Monopolar, 33cm Length
AUTOSUTURE	ENDO SHEARS 5mm	Monopolar, 33cm Length
CONMED	Curved Metzenbaum, 5mm	Monopolar, 32cm Length
CONMED	Curved Metzenbaum, Narrow Tip, 5mm	Monopolar, 32cm Length
CONMED	Curved Metzenbaum, Mini, 5mm	Monopolar, 32cm Length
CONMED	Maryland Dissector, 5mm	Monopolar, 32cm Length
ETHICON	Dissector, 5mm	Monopolar, 33cm Length
ETHICON	Scissors, 5mm	Monopolar, 33cm Length
GYRUS	Bipolar Cutting Forceps, 5mm	24cm Length
GYRUS	Bipolar Cutting Forceps, 5mm	33cm Length
GYRUS	Bipolar Cutting Forceps, 10mm	15cm Length
GYRUS	Bipolar Cutting Forceps, 10mm	33cm Length
GYRUS	Bipolar Needle Electrode, 5mm	33cm Length

Indications for Use

510(k) Number (if known): K052690

Device Name: SureTek Reprocessed Laparoscopic Instruments

Indications for Use:

SureTek Reprocessed Laparoscopic Instruments are intended for use during general and laparoscopic surgery for cutting, grasping, dissection and electrocautery of tissue.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052690